

AMERICAN FEED INDUSTRY ASSOCIATION

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October 28, 2002

Dockets Management Branch (HFA - 305) Food and Drug Administration 5630 Fishers Lane Room 1061 Rockville, MD 20852

Re: <u>Docket No. 02N-0209</u>; Request for Comment on First Amendment Issues – Response

The American Feed Industry Association (AFIA) offers this response to the comments filed with the Food and Drug Administration (FDA) concerning the agency's Request for Comment on First Amendment Issues (hereinafter "Comment Request"), 67 Fed. Reg. 34,942 (May 16, 2002). In the comments it submitted on September 13, 2002, AFIA set out how FDA's policies conflict with the First Amendment by prohibiting the flow of health information about pet foods, animal feed, and feed ingredients. Unlike foods and dietary supplements for human consumption, there is no mechanism short of a lengthy pre-approval process for pet food, animal feed manufacturers, and ingredient suppliers to disseminate health information about the foods animals consume. Only animal products subject to an FDA-approved New Animal Drug Application (NADA) or an Abbreviated New Animal Drug Application (ANADA) may make health claims and claims of nutritional support. AFIA urges FDA to examine its animal feed and animal drug regulations and policies for it is unlikely that the scheme could survive a First Amendment challenge.

1. There is a Consensus for Change

AFIA was not alone in its call for change to these out-of date-regulations and policies that prohibit manufacturers from disseminating, and animal owners from receiving, truthful information about animal feed. AFIA draws FDA's attention to the comments of the National Grain and Feed Association (NGFA), the Pet Food Institute (PFI), and the joint comment of Julian M. Whitaker, M.D., Durk Pearson and Sandy Shaw, Pure Encapsulations, Inc., Wellness Lifestyles, Inc. Suarez Corporation Industries, Inc., Life Enhancement Products, Inc., and Life Extension Foundation (hereinafter "Joint Comment"). These comments all unanimously express the same view – FDA prohibitions upon the dissemination of truthful information about the healthful qualities of pet food, animal feed products, and feed ingredients are unconstitutional, harm consumers, stifle innovation, and unfairly discriminate against manufacturers and distributors of animal feeds and supplements by prohibiting them from communicating what the manufacturers and distributors of human foods and supplements may communicate.

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The Joint Comment stated:

Even under the heightened intermediate scrutiny afforded commercial speech, FDA's failure to apply its health claims review and structure/function claim regime to pet foods and supplements violates the First Amendment. Communication of health and structure/function claims is not unlawful activity or misleading speech. While FDA has a compelling interest in protecting the public, a complete prohibition on structure/function claims for pet foods and dietary supplements absent pre-market drug approval does not directly and materially advance FDA's interests.

. . .

[T]here are obvious, less speech restrictive alternatives to FDA's blanket ban on structure/function and health claims for pet foods and dietary supplements. FDA can permit such claims relying on the very same procedures it now employs to permit structure/function claims for human foods and supplements and to authorize and allow health claims for those same products.

Joint Comment, pgs. 79-80. See also PFI Comment, pgs. 1, 3-4; NGFA Commet, pg. 2 ("The recent history of food labeling legislation and regulation in the United States has created an unlevel playing field when it comes to the type of commercial information allowed for dietary supplements compared to animal feed and feed ingredients").

2. Reform Through Guidance and Rulemaking

AFIA urges FDA to heed this call for reform and rectify these unconstitutional prohibitions and inequalities. AFIA proposes that FDA issue first an interim guidance and eventually regulations addressing and expanding the claims that animal feeds, pet foods, and supplements may bear without undertaking the arduous NADA or ANADA process. As addressing product claims on pet foods and animal feeds via a mechanism other than an NADA or ANADA is a fundamental change that potentially affects many interests, AFIA suggests that FDA also consider the appropriateness of undertaking this reform through negotiated rulemaking.

FDA should look to the procedures and standards set out in the human food regulations regarding health claims and permissible dietary supplement claims. AFIA believes such a guidance and regulation should consider the following approach:

- A product sponsor must notify FDA in advance of its intent to include a claim on its product label and labeling.
- If FDA does not object to the claim within a specified period of time, the product sponsor may proceed to market, assuming the risk that FDA may later object to the product and/or take enforcement action.
- Borrowing from the standards of the Federal Trade Commission, the product sponsor must have competent and reliable scientific evidence substantiating its claims.
- The product sponsor must be able to demonstrate by competent and reliable scientific evidence that the product is safe under the terms of usage described in the label.
- An animal dietary supplement or food may not claim the product treats, cures, prevents, or mitigates disease.²

In its Comment to FDA, the Animal Health Institute (AHI), an association whose membership includes many animal pharmaceutical manufacturers, supported FDA's current (and in AFIA's view, unsupportable) position that animal feed and supplements may not bear health claims and structure/function claims permitted for human supplements under the Dietary Supplement Health and Education Act (DSHEA). AHI and its members specifically object to those products that "make claims of disease prevention, treatment, or production enhancement." AHI Comment, pg. 3. Under current regulations, however, dietary supplements for human use may not bear claims of disease treatment, prevention, cure, or mitigation. See 21 C.F.R. § 101.93(g)(2). Thus, even if FDA ceased its arbitrary distinctions and extended DSHEA to animal food supplements, under current interpretations, animal supplements could not bear disease claims.

² Current human dietary supplement regulations specify that a dietary supplement may not make a "disease" claim. However, some commentators have urged that such restrictions are themselves unconstitutional. See, e.g., Joint Comment, pgs. 70-76. A good argument can be made that FDA may not constitutionally limit properly qualified, substantiated product claims that go beyond what FDA believes DSHEA permits. The extent to which FDA may restrict truthful, qualified information about products without violating the Constitution is an issue that may be especially amenable to consideration and resolution through the negotiated rulemaking process.

• Product labels must bear plain disclosures that the product is not an animal drug and has not been approved by the FDA.

AFIA further proposes that, for any claim FDA has not pre-approved, the product sponsor must make the underlying scientific information substantiating the claim available for public review. There are two significant reasons for this transparency in claim substantiation. First, vigorous policing of product claims is more likely, and the potential for false or misleading claims deterred, if the data supporting product claims is public.

Second, making data publicly available is consistent with the FDC Act. For example, a drug for animal or human use is not a "new animal drug" or "new drug," respectively, that requires FDA premarket approval if the product is, in relevant part, "generally recognized" as safe and effective for its intended uses by qualified experts. See 21 U.S.C. § 321(v) (definition of "new animal drug"); § 321(p) (definition of "new drug"); § 360b (premarket approval requirements for "new animal drugs"); § 355 (premarket approval requirements for "new drugs"). In similar fashion, an animal feed or human food ingredient is not a "food additive" requiring FDA premarket approval if it is "generally recognized" as safe. See 21 U.S.C. § 321(s) (definition of "food additive"); § 348 (premarket approval requirements for "food additives"). The Supreme Court has stated that "general recognition" status (to avoid FDA premarket approval requirements) must be based on information in the public domain. Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645, 652 (1973).

The proposals of other commentators are consistent with AFIA's suggestions. PFI urges FDA to "provide to pet food manufacturers the same kind of certainty human food manufacturers have ... while still insuring that claims are not false or misleading." PFI Comment, pg. 4. "NGFA believes that FDA should develop and issue criteria that permit truthful, non-misleading information on animal feed and pet food labels and advertising that are consistent with the commercial free-speech doctrine and do not require FDA's preapproval through a NADA or ANADA process." NGFA Comment, pg. 2.

The Joint Comment offers concrete suggestions:

There is presently no statutory or regulatory provision for the regulation of health claims for animal foods and dietary supplements. As a general rule, they are disallowed except by the ad hoc (and largely arbitrary) exercise of case by case determinations in the discretion of the Department of Veterinary Medicine. By rule, FDA should adopt a simple provision stating that health claims for animal foods and dietary supplements shall be subject to the same review, procedures, and precedent as apply to health claims for human foods and dietary supplements, namely 21 C.F.R. §§ 101.14; 101.70;

<u>Pearson</u> I, II, and III [<u>Pearson v. Shalala</u>, 130 F. Supp.2d 105 (D.D.C. 2001) and progeny].

There is presently no statutory or regulatory provision for the regulation of structure/function claims for animal foods and dietary supplements. As a general rule, they are disallowed except by the ad hoc (and largely arbitrary) exercise of case by case determinations in the discretion of the Department of Veterinary Medicine. By rule, FDA should adopt a simple provision stating that structure/function claims for animal foods and dietary supplements shall be subject to the same notification procedures and treatment as apply to structure/function claims for human foods and dietary supplements, namely 21 C.F.R. § 101.93.

Joint Comment, pgs. 147-148.

3. Other First Amendment Concerns

AFIA further concurs with the Joint Comment and others who argue cogently that FDA violates the First Amendment by suppressing information on "off-label" uses and prohibiting manufacturers from distributing scientific literature on off-label uses. See, e.g., Joint Comment, pgs. 96-106. Currently, manufacturers risk enforcement action if they disseminate scientific articles about the health benefits of an ingredient in a pet food, animal feed, or supplement, even if the article has a prominent disclaimer that the product is not an animal drug and that FDA has not approved the product or its claims. These prohibitions upon the dissemination of scientific research offend the Constitution. AFIA joins with others who urge their elimination.

In sum, there is a consensus for changing the way FDA limits the dissemination of truthful, non-misleading information about the healthful qualities of pet foods, animal feeds, feed ingredients, and supplements. The current regulatory environment harms manufacturers, suppliers, animal owners, and animals.

The uncertainty under which the animal feed industry operates chills commercial speech, inhibits the flow of valuable information, and stifles innovation. AFIA urges FDA to look carefully at the excellent arguments and models set out in the comments submitted on these important issues and then to undertake meaningful reform of the unconstitutional prohibitions upon the animal feed, pet food, and food ingredient industries.

Sincerely,

Vice President, Reed Control and Nutrition

American Feed Industry Association